UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LYNORA ADESINA et al., Plaintiff,	:	98 Civ. 5535 (JFK)
-against-	:	**OPINION AND ORDER**
ALADAN CORPORATION et al., Defendants.	:	

APPEARANCES:

For Plaintiff Lynora Adesina:

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For Defendant Aladan Corp.:

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JOHN F. KEENAN, United States District Judge

JOHN F. KEENAN, United States District Judge:

INTRODUCTION

This products liability case arises from Plaintiff's use of latex gloves manufactured by Defendant that allegedly caused Plaintiff to suffer serious health consequences. Defendant Aladan brings six motions: four motions for summary judgment or partial summary judgment, and two motions to exclude the testimony of Plaintiff's expert witnesses. For the reasons discussed below, Defendant's four summary judgment motions are denied, and Defendant's two motions to exclude expert testimony are denied in part and granted in part.

BACKGROUND

This case was originally filed in New York State Supreme Court, then removed to the Southern District of New York, then transferred by the Multi-District Litigation ("MDL") Panel to the Eastern District of Pennsylvania, and finally remanded back to the Southern District of New York by the MDL panel.

Although the complaint was brought by two plaintiffs against several defendants, the only parties now remaining in the case are the parties to the present motions: Plaintiff Lenora Adesina and Defendant Aladan Corporation ("Aladan").

Ms. Adesina formerly worked as a nurse, providing home health care services. To perform this job, between September 1992 and March 1997, Ms. Adesina used natural rubber latex

("NRL") gloves manufactured by Aladan. (Def.'s 56.1 Statement (Failure Warn) ¶¶ 1-2; Pl.'s 56.1 Statement (Failure Warn) ¶¶ 1-2.)

Over time, Ms. Adesina allegedly developed an allergy to natural rubber latex and suffered adverse health consequences as a result of her reaction to the natural rubber latex in the gloves. (Compl. ¶ 14.) In March 1997, she was diagnosed with Type I latex allergy, as well as Type IV contact dermatitis (Def's 56.1 Statement ¶ 5; Pl.'s 56.1 Statement ¶ 5), and has suffered injuries including asthma, rashes, skin infections and difficulty breathing (Compl. ¶ 4).

As a result of her alleged allergies, Ms. Adesina sued Aladan, charging (1) negligence and gross negligence, (2) strict liability, (3) failure to warn and misrepresentation, and (4) breach of implied and express warranties.[1] She seeks $5 million in compensatory damages and $10 million in punitive damages.

In the six motions now before the Court, Aladan argues that (i) Plaintiff's failure to warn claims are preempted by federal law; (ii) Plaintiff's failure to warn claims should be dismissed on the merits; (iii) Plaintiff's claims should be dismissed because Plaintiff offers no admissible evidence of

[1] The complaint originally included a fifth cause of action for loss of consortium, brought by Plaintiff's husband, John Adesina. That claim has been dismissed by stipulation and John Adesina is no longer a party to this action.

latex allergy; (iv) the testimony of Dr. Ellen Epstein should be excluded under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1983); (v) Plaintiff's claims should be dismissed because Plaintiff offers no admissible evidence of a product defect; and (vi) the testimony of Charles Kyper should be excluded under Daubert.

Plaintiff opposes the motions. The Court addresses each motion in turn below.

DISCUSSION

I. Motion for Partial Summary Judgment Contending Preemption of Failure to Warn Claims

Latex gloves are medical devices under the framework established by the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938. See 21 C.F.R. § 880.6250. In 1993, the Food and Drug Administration ("FDA") published a 200-page manual titled Regulatory Requirements for Medical Gloves: A Workshop Manual ("Glove Manual"). This manual contains an extensive list of device-specific requirements concerning latex gloves. (Def.'s 56.1 Statement ¶ 4; Pl.'s Am. 56.1 Statement ¶ 4.)

Aladan moves for partial summary judgment on all four counts in plaintiff's complaint to the extent each of the four counts encompasses a failure to warn claim. In Aladan's opinion, "the heart of Mrs. Adesina's allegations is that Defendants'[sic] products were defective in that they failed to contain warnings

advising of a potential for developing latex allergy."[2] (Def.'s Mem. 2.) Aladan argues that Ms. Adesina's claims are preempted by the Glove Manual and the Food, Drug, and Cosmetic Act because her claims impose warning and labeling requirements on Aladan under state tort law, which are different from, or in addition to, those required by the FDA. (Def's Mem. L. 2.) The Court, drawing all inferences in favor of Ms. Adesina, the non-movant, as is required on a motion for summary judgment, finds that Ms. Adesina's claims are not preempted.

A. Summary Judgment Standard

A motion for summary judgment may be granted under Rule 56 of the Federal Rules of Civil Procedure if the entire record demonstrates that "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). When viewing the evidence, the Court must "assess the record in the light most favorable to the non-movant and . . . draw all reasonable inferences in its favor." Del. & Hudson Ry. Co. v. Consol. Rail Corp., 902 F.2d 174, 177 (2d Cir. 1990); see McLee v. Chrysler Corp., 109 F.3d 130, 134 (2d Cir. 1997); see also Anderson, 477 U.S. at 255. "[A]t the summary judgment

[2] According to Aladan, "Although Plaintiff's Complaint is vague, for the purposes of this Motion only, it is presumed that plaintiff's first cause of action for negligence includes a failure to warn claim." (Def.'s Mem. L. 2, note 2 (citing Compl. ¶ 32.))

stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson, 477 U.S. at 249. To survive a motion for summary judgment, the plaintiff "need only present evidence from which a jury might return a verdict in his favor. If he does so, there is a genuine issue of fact that requires a trial." Id. at 257.

B. Relevant Statutory and Regulatory Regime

Congress's first major foray into the field of public health was the Food and Drug Act of 1906, "a broad prohibition against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug." Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996). The scope of the Food and Drug Act was broadened in 1938 "to include misbranded or adulterated medical devices and cosmetics," and the Act was appropriately renamed the Food, Drug, and Cosmetic Act ("FDCA"). Id. Almost forty years later, Congress expanded the law again and passed the amendments at issue here, the Medical Device Amendments of 1976 ("MDA"), which authorize control over the introduction of new medical devices. Id. at 475-76.

1. The Medical Device Amendments

Under the MDA, medical devices are categorized into three classes. Id. at 476. Class I devices pose "no unreasonable risk of illness or injury" to the public, and as such are subject

to minimal regulation. Id. at 476-77. Potentially more harmful devices are designated as Class II, and must comply with a somewhat higher level of federal regulation. Id. at 477. Class III devices either "presen[t] a potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." Id. at 477 (internal citations omitted). Because Class III devices pose a greater potential risk, such devices are subject to rigorous regulation under the MDA. Id. Defendant contends, and Plaintiff does not dispute, that latex gloves are Class I devices under this framework. (Pl.'s Mem. L. 1; Def.'s 56.1 Statement ¶ 3.)

To bring a new Class I or Class II device to market, a manufacturer must satisfy a limited review by submitting pre-market notification to the FDA, pursuant to 21 U.S.C. § 360(k).[3] Medtronic, 518 U.S. at 478. The FDA spends approximately twenty hours on this review process. Id. at 478-79. Contrast this with the 1200 hours the FDA spends reviewing a new Class III device for pre-market approval ("PMA process"). Id. Although, in circumstances where a Class III device is "substantially equivalent" to one already on the market, the manufacturer of the

[3] This process is also referred to as the § 510(k) process after the number in the section of the original act. Medtronic, 518 U.S. at 478.

device need not seek pre-market approval, but instead can enter the market via the more lenient § 360(k) pre-market notification process. Id. at 478.

2. The Glove Manual

In 1992, the FDA published the Glove Manual, which "covers the basic regulatory requirements" and serves as a "reference source for information" for manufacturers of latex gloves. Glove Manual, Preface at iii. According to the Glove Manual itself, it is "one of several used in the Division of Small Manufacturers Assistance Latex Device Workshops," and "[t]he educational information in this manual is not an official statement binding on the FDA." Glove Manual, Abstract at iv. The Glove Manual contains "information on the regulatory requirements for patient examination gloves, surgeon's gloves, and non-medical gloves," id. at 1-2, and gives guidance for glove labeling, including items that are "required," id. at 2-3, items that are "recommended," id., and "additional labeling claims," including "hypoallergenicity," id. at 3-6.

C. Preemption Doctrine

1. Constitutional Background

The preemption doctrine, speaking as a matter of Constitutional theory, lives a double life. The Supremacy Clause, U.S. Const. Art. VI, cl. 2, confirms that "the laws of the United States . . . shall be the supreme Law of the Land."

The Tenth Amendment, however, reserves "powers not delegated to the United States by the Constitution . . . to the States respectively, or to the people." Between these two poles lies the land of the preemption doctrine, by which federal law does or does not take the place of the law of a state. On the one hand, the Supremacy Clause favors preemption in fields that are inherently federal in character, while on the other hand, the Tenth Amendment presumes that areas of law traditionally governed by the states, including common law torts and areas related to public health and safety, will not be displaced by a federal statute. Hillsborough County Fla. v. Automated Med. Lab., 471 U.S. 707, 713-15 (1985); Metro. Life Ins. Co. v. Mass., 471 U.S. 724, 756 (1985) ("States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.") (internal quotations omitted). Thus, "a court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find preemption." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993). In areas such as these, one "start[s] with the assumption that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." Hillsborough, 471 U.S. at 715 (internal quotations omitted).

Federal regulations, likewise, can be the basis for

preemption of state law. Id. at 713. Because federal agencies "normally address problems in a detailed manner and can speak through a variety of means," courts can expect a certain level of clarity from an agency that intends to make its regulations the exclusive law in a given field. Id. at 718. When an agency does not address the issue, courts are reluctant to make a finding of preemption based on "the mere volume and complexity of [the agency's] regulations." Id. at 718. "To infer preemption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." Id. at 708.

2. Preemptive Effect of the FDCA

a. Statute and Regulations

The relevant statutory language as to the preemptive effect of the FDCA reads as follows:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

According to the FDA's implementing regulations, "State

. . . requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d).

The regulations also clarify that the FDCA,

> does not preempt state . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

Id.

In sum, for preemption to occur, the FDA must specifically regulate a particular area in the field of public health, and the state must have put requirements in place that relate specifically to the same area that add to or differ from the federal regulations. The issue presently under consideration concerns the first portion of the preemption test: whether the FDA has specifically regulated latex gloves in a way that preempts state tort law claims against a manufacturer of latex gloves.

b. Case Law

The leading case on point is Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). In Medtronic, a recipient of a pacemaker, a "substantially equivalent" Class III medical device that entered the market through the lenient § 360(k) process, sued the

manufacturer, asserting common law negligence and strict liability claims after the pacemaker failed. Id. at 480-81. The manufacturer moved for summary judgment, arguing that state common law tort claims were preempted by the Medical Device Amendments. Guided by "the historic primacy of state regulation of matters of health and safety," and the Supreme Court's mantra that "the purpose of Congress is the ultimate touchstone in every preemption case," id. at 485-86, the Supreme Court held that the MDA's "substantial equivalence" § 360(k) process does not preempt state common law negligence claims because the process "d[oes] not 'require' [medical devices] to take any particular form for any particular reason; the agency simply allow[s] the [substantially similar devices], . . . , to be marketed without running the gauntlet of the PMA [pre-market approval] process,"[4] id. at 493-94 (internal quotations omitted).

In Richman v. W.L. Gore & Assocs., 988 F. Supp. 753 (S.D.N.Y. 1997) (Leisure, J.), the Court distinguished Medtronic, finding state common law tort causes of action preempted by the MDA. The Richman court reasoned that the Class III medical device at issue, an artificial ligament, had undergone the rigorous PMA process, whereas the Class III device at issue in

[4] Although Medtronic is, in part, a plurality decision, this portion of the decision, Part V was decided by a majority. Medtronic, 518 U.S. at 474, 492-94 (Stevens, J. joined by Kennedy, J., Souter, J., Ginsberg, J., Breyer, J.).

Medtronic

> reached the marketplace because it was "substantially equivalent" to another device, and the [Medtronic] Court observed that the 510(k) process focused only on equivalence, not on safety. Therefore, [in Medtronic] no device-specific regulation by the FDA existed, which is a condition for preemption of state requirements by the MDA.

Id. at 758. Accordingly, the Richman court held that the "significantly more demanding" process to which the artificial ligament was subjected "constitutes the type of specific federal regulation of a product that can have a preemptive effect under the MDA." Id.

In Whitson v. Safeskil Corp., 313 F. Supp. 2d 473 (M.D. Pa. 2004), a case relied on heavily by Aladan in its briefs, a Pennsylvania District Court held that a nurse's breach of implied warranty claims brought against latex glove manufacturers were preempted by the Glove Manual. The Glove Manual, the Court reasoned, makes specific "requirements for the labeling on patient examination gloves," and therefore preempts state law. Id. at 477.

D. Analysis of Preemption Motion

1. Significance of the Glove Manual

This Court believes Whitson erroneously interprets Medtronic and overstates the impact of the Glove Manual. The Whitson court treats the Glove Manual as a bona fide set of FDA regulations, rather than as a less potent handbook. As

Plaintiff's counsel correctly asserts, the Glove Manual is not a federal regulation to the extent that it has not undergone, as is characteristic of federal agency regulations, a period of "notice and comment." The Glove Manual is not published in the Code of Federal Regulations, and moreover, refers to itself as an "educational information . . . manual . . . not an official statement binding on the FDA." Glove Manual, Abstract at iv. This Court is hard-pressed to presume Congressional intent to preempt state law based on a manual of questionable regulatory authority.

From a separation of powers perspective, the preemptive effect of the Glove Manual is further undercut by the presumption against preemption in fields, such as public health, traditionally within the purview of state police powers. Indeed, as a self-described "reference source for information," Glove Manual, Preface at iii, the Glove Manual can hardly be said to outstrip the FDA's "overarching concern" that preemption occur only where a "specific federal interest" is at stake. See Medtronic, 518 U.S. at 500. The recommendations of the Glove Manual do not rise to the level of a "requirement" such that Aladan must prevail as a matter of law. The Manual does not establish a regulatory system with the certainty that this motion for summary judgment requires.

2. Effect of the § 360(k) Process

After removing the Glove Manual from consideration, only the pre-market notification process required by § 360(k) remains as a possible preemptive mechanism. By comparing the facts and holdings from Medtronic and Richman, it is apparent that the § 360(k) process is not the kind of requirement that preempts state law. Richman involved a traditional Class III device regulated by the FDA's rigorous 1200 hour pre-market approval process. That in-depth process, the Richman Court held, preempted state law. The Class III "substantially similar" device in Medtronic, however, was regulated only by the 120 hour § 360k process, as were the Class I latex gloves manufactured by Aladan. This significantly less demanding process, the Supreme Court held, does not preempt state tort law claims. Medtronic, 518 U.S. at 494-94.

Aladan's motion for summary judgment on the basis of preemption is denied.

II. Motion for Partial Summary Judgment on Failure to Warn Claims

Ms. Adesina alleges that Aladan failed to provide adequate warnings of the dangers associated with NRL gloves, and that as a result she suffered a Type I latex allergy from her use of and exposure to the gloves. Aladan moves for partial summary

judgment on the failure to warn claims, contending that Ms. Adesina cannot produce admissible evidence establishing Defendant's duty to warn or that the alleged failure to warn was a proximate cause of her injuries.

The Court relies on its previous overview of the summary judgment standard, and now turns to the relevant tort law standards.

A. New York[5] Failure to Warn Standard

To prevail on her failure to warn claims, Ms. Adesina must show that (1) Aladan had a duty to warn against dangers resulting from foreseeable uses about which it knew or should have known; and (2) that failure to do so was the proximate cause of Ms. Adesina's latex allergy. Santoro v. Donnelly, 340 F. Supp. 2d 464, 485 (S.D.N.Y. 2004); Crespo v. Chrysler Corp., No. 97 Civ. 8246 (S.D.N.Y. Aug. 25, 1998). "'A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its products of which it knew or should have known.'" Id. (quoting Liriano v. Hobart Corp., 92 N.Y.2d 232, 237 (1998)).

Failure to warn law includes a presumption that "'a user would have heeded warnings if they had been given, and that the injury would not have occurred.'" G.E. Capital Corp. v. A.O.

[5] In considering a motion for summary judgment on a diversity action, the federal court looks to the relevant state substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The parties agree that this case is governed by New York law.

Smith Corp., No. 01 Civ. 1849, 2003 WL 21498901 at *5 (S.D.N.Y. July 1, 2003) (Preska, J.). A defendant "may rebut this presumption by introducing specific facts showing that the warning would have been futile." Id. (internal quotations omitted). If a failure to warn would have been futile, plaintiff cannot prove proximate causation. Id. at *6.

B. Analysis

1. Whether Aladan Had a Duty to Warn

a. Aladan's Knowledge of the Danger

Aladan contends that Ms. Adesina cannot establish Aladan's duty to warn about the dangers of latex gloves because she offers no admissible proof of the "timing and extent of [Aladan's] knowledge." (Def.'s Mem. L. 3.) According to Aladan, such proof is necessary because "[i]mplicit in the [Santoro and Crespo] decisions setting forth the elements of a failure to warn claim is the requirement that a failure to warn plaintiff prove the timing and extent of the defendant's knowledge of the alleged danger." (Def.'s Mem. L. 3.) Notably, Aladan cites no authority for this inference, and neither Santoro nor Crespo warrants such extrapolation.

What is explicit in the Santoro and Crespo decisions is that evidence supporting a duty to warn need not prove a defendant's actual knowledge: "[C]laimant must demonstrate that a manufacturer has a duty to warn against dangers resulting from

foreseeable uses about which it knew or should have known." Santoro, 340 F. Supp. 2d at 485 (emphasis added). As this language makes clear, it is not necessary to prove the dates when Aladan specifically knew about the dangers of latex gloves because Ms. Adesina can also prevail on her failure to warn claims by establishing when Aladan should have known about the dangers.

Therefore, contrary to Aladan's assertions, it is not fatal to Ms. Adesina's claim that she "has not identified any witness in this matter who has reviewed any Defendant-specific materials to determine the timing and extent of Defendant's knowledge regarding the NRL allergy issue." (Def.'s Mem. L. 3-4.) Nor is it true, as Defendant concludes, that "[a]bsent evidence of what [Aladan] knew about NRL allergy and when [Aladan] knew it, Plaintiff cannot establish that Aladan was required to place warning labels" on its gloves. (Def.'s Mem. L. 4.)

b. Expert Testimony to Establish When Defendant Reasonably Should Have Known of the Danger

Aladan also argues that Ms. Adesina cannot establish "the timing and extent of the information that defendant . . . reasonably should have known regarding the NRL allergy," because she cannot provide the necessary expert testimony on this issue. (Def.'s Mem. L. 4.) Aladan claims that expert testimony is necessary because the dangers Defendant allegedly should have

warned consumers about "are complex and scientific in nature." (Def's Mem. L. 2.) According to Aladan, the vast majority of information about NRL was only available during the relevant time frame in reports and articles from scientific and medical journals. "This complex and highly technical information would be impossible for a jury to evaluate in the absence of specialized knowledge." (Def.'s Mem. L. 4-5.) In essence, Aladan is arguing that Ms. Adesina's failure to warn claims cannot proceed, as a matter of law, without an expert who can explain in layman's terms what type of information was available regarding the NRL allergy for the purposes of establishing whether Aladan should reasonably have known about the dangers of latex gloves.

Aladan bases this argument on Federal Rule of Evidence 702, which states as follows:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, experience, training, or education, may testify thereto in the form of an opinion or otherwise . . . .

Fed. R. Evid. 702 (emphasis added). As the Court's emphasis illustrates, the text of the rule itself does not require an expert to assist the trier of fact.

Aladan also quotes from the 1972 Advisory Committee Note to Rule 702: "[A]n intelligent evaluation of the facts is often difficult or impossible without the application of some . .

. specialized knowledge." Id. Aladan seems to offer this excerpt to support the proposition that intelligent evaluation is impossible without an expert. However, the next sentence in the Advisory Committee Note continues, "The most common source of this knowledge is the expert witness, although there are other techniques for supplying it." Id. (emphasis added). Moreover, the Advisory Note says intelligent evaluation is "often" difficult or impossible, and not that it is "always" difficult or impossible without specialized knowledge. The Court infers in favor of Ms. Adesina, the non-movant, that the failure to warn claims at issue here do not require the specialized knowledge of an expert.

2. Whether Failure to Warn Proximately Caused Ms. Adesina's Latex Allergy

Aladan contends that Ms. Adesina's testimony at her deposition proves that warnings on Aladan's latex gloves would have been futile because Ms. Adesina states that she would have continued to use the gloves despite warnings. She testified as follows:

> Q: If the Aladan box had a warning that said that it might cause you to have an allergic reaction and that if you had one, you should stop using it and see a doctor, would you have still used the Aladan glove?
>
> A: Probably.

(Ex. 1 at T119-120:8-15.)

Plaintiff responds that the "probably" permits the inference that Ms. Adesina would continue wearing latex gloves only until she had an allergic reaction. Therefore, she would be in compliance with the hypothetical warnings suggested to her at the deposition. Because Ms. Adesina is the non-movant, the Court makes this inference in her favor. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.").

Ms. Adesina also contends that the inference is supported by her testimony that she stopped using latex gloves in 1997 when she was diagnosed as having latex reactions by Dr. Saleh Baselious, who wrote a letter ordering that Ms. Adesina not come into contact with latex materials. Defendant counters that another doctor, Dr. Pawlecki, testified that Ms. Adesina told him she was still using latex gloves in 1998. Even if the medical statement exception to the hearsay rule applies, see Fed. R. Evid. 803(4), this testimony creates a factual dispute. The Court denies Aladan's summary judgment motion seeking dismissal of Ms. Adesina's failure to warn claims.

III. Motion for Summary Judgment or Partial Summary Judgment on Whether There Is Evidence of Latex Allergy

Defendants move for summary judgment or partial summary

judgment on the ground that Ms. Adesina's latex allergy is not sustainable to any reasonable degree of medical or scientific certainty. Aladan argues that: 1) there is no evidence that Ms. Adesina was treated for latex allergy or that she suffered from such a disability; 2) there is no admissible evidence that she had a reliable Radioallergosorbent ("RAST") test, an allegedly essential ingredient to a diagnosis of a Type I latex allergy; and 3) there is no admissible evidence that Plaintiff suffers from a Type IV delayed chemical hypersensitivity/contact dermatitis.

The Court again relies on its previous overview of the summary judgment standard, and now addresses the merits of Aladan's summary judgment motion as to the sustainability of Ms. Adesina's Type I latex allergy and Type IV contact dermatitis.

A. <u>Evidence of Medical Treatment and Disability</u>

Aladan argues that Ms. Adesina's employer, Dr. Aranow, knew nothing of Ms. Adesina's condition until subpoenaed for his deposition, even though he had been her employer for six years and her primary physician for twelve. He also never treated her for latex allergy and his review of her file during deposition confirmed that nothing therein reflected her condition. (Def's Mem. L. 11.) In addition, Ms. Adesina's supervisor at the Amityville Family Practice (where she has worked since 1998) has testified that she never missed work due to a latex allergy.

(Def's Mem. L. 14.)

Plaintiff opposes summary judgment, citing additional testimony from Dr. Aranow, in which he states that Ms. Adesina was noted to have "resolving asthmatic bronchitis" in 1995 and the symptoms were consistent with a "[c]ombination of allergic symptoms and asthma." (Pl.'s Mem. L. 2 (quoting Ex. G at 53.))

This is a factual dispute. Weight, not admissibility is the issue here. Neither Dr. Aranow's testimony nor the testimony of Ms. Adesina's supervisor is dispositive evidence that Ms. Adesina, as a matter of law, has or has not suffered from a latex allergy.

B. Disputed RAST Test

Ms. Adesina went to see Dr. Saleh Baselious -- an ear, nose, and throat specialist -- for the first time on March 22, 2006, to obtain a confirmed diagnosis of a latex allergy. (Pl.'s 56.1 Statement ¶¶ 3, 5.) In his office, Dr. Baselious performed a RAST test, a test commonly used and relied on, "at least in part," to diagnose latex allergy.[6] (Def.'s 56.1 Statement ¶ 7.) The RAST test checks a person's blood serum for what both parties refer to as IgE antibodies specific to the latex allergen.

[6] According to the parties, diagnosis of a latex allergy may also be made through use of a percutaneous scratch test to latex proteins, but because there is no standardized latex antigen available in the United States for scratch testing, latex allergy is usually documented in the United States with a RAST test. (Def.'s 56.1 Statement III ¶ 8.)

(Def.'s 56.1 Statement ¶ 7.) According to Dr. Baselious, Ms. Adesina tested positive for these antibodies. Based, in part on the RAST test and in part on Ms. Adesina's medical history, Dr. Baselious diagnosed her with Type I latex allergy. (Pl.'s Mem. L. 1-2.)

Aladan argues that the RAST test should be excluded under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1983), and Federal Rule of Evidence 702.

1. *Daubert* Standard

In Daubert, the Supreme Court held that expert testimony is admissible if the judge, acting as a gatekeeper, determines the testimony is both reliable and relevant. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (citing Daubert, 509 U.S. at 597). Daubert overruled Frye v. United States, 54 App. D.C. 46, 47, 293 F. 1013, 1014 (1923), under which expert testimony was admitted only if it was based on a "generally accepted" scientific technique. Daubert, 509 U.S. at 584-87.

In response to Daubert, Federal Rule of Evidence 702, which governs the admissibility of expert testimony, was amended and now prescribes as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is

> the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

These requirements have been described as "qualifications, reliability, and fit." Elcock v. K-mart Corp., 233 F.3d 734, 741 (3d Cir. 2000). To be qualified, the expert must be "well-versed in the particular discipline relevant to their testimony." Smith v. Rasmussen, 249 F.3d 755, 759 (8th Cir. 2001); see also Zaremba v. General Motors, Corp., 360 F.3d 355, 360 (2d Cir. 2004).

To aid the judge in assessing the reliability of expert testimony, Daubert set forth a number of factors courts may consider, including (1) whether the methodology "can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) a technique's "known or potential rate of error," and "the existence and maintenance of standards controlling the technique's operation;" and/or (4) whether a theory has gained "general acceptance"[7] in the relevant scientific community. Daubert, 509 U.S. at 593-94. These factors are not a "definitive checklist" and are to be applied flexibly depending on the facts of a particular case. Id.

[7] Under Daubert, "general acceptance" has become just one factor to consider, whereas under Fyre, "general acceptance" was the sole means for evaluating whether expert testimony was admissible.

For expert testimony to "fit," the testimony must have a valid "connection to the pertinent inquiry" and be "sufficiently tied to the facts of the case so that it will aid the jury in resolving a factual dispute." Id. at 591-592. "This condition goes primarily to relevance." Id. at 591. In assessing relevance, the judge looks to Rule 401, which deems evidence relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401.

The flexible Daubert test does not require the judge to step into a white lab coat and perform a rigorous scientific analysis of the proposed expert testimony, but rather "gives the district court the discretion needed to ensure that the courtroom door remains closed to junk science while admitting reliable expert testimony that will assist the trier of fact." Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002).

Aladan argues that the RAST test performed by Dr. Baselious should be excluded under Daubert because Dr. Baselious was not qualified to administer the test, the particular RAST test utilized was not reliable, and Dr. Baselious' diagnosis was not based on reliable application of accepted principles and methods to the facts of the case. (Def.'s Mem. L. 6.)

2. Analysis

a. Dr. Baselious' Qualifications

According to Aladan, Dr. Baselious "is not qualified in allergy, immunology or laboratory science." (Def.'s Mem. L. 6.) Aladan points out that Dr. Baselious is an ear, nose, and throat specialist, "not an allergist" with "special training in allergy," and has never published any articles on latex allergy or any other medical subject. (Def.'s Mem. L. 6.) Aladan also contends that Dr. Baselious' deposition testimony "indicated that he had only a rudimentary understanding of the nature of the purported 'RAST' test, allergies in general, and the diagnosis and treatment of allergies and latex allergy in particular." (Def.'s Mem. L. 6.)

Though not specifically an allergist, Dr. Baselious as an ear, nose, and throat doctor, specializes in a discipline in which he is likely familiar with the diagnosis of allergies. If Dr. Baselious' deposition testimony indeed "indicated" his "rudimentary" understanding of allergies, this is a subject for cross-examination and goes to weight, not admissibility. The same applies to the fact that Dr. Baselious has not published any articles. See Daubert, 509 U.S. at 596 ("Vigorous cross-examination" and "presentation of contrary evidence" are among the means for "attacking shaky but admissible evidence.").

b. Reliability

Aladan contends that the RAST test performed by Dr. Baselious was not derived from the application of a scientifically valid and reliable method because the particular RAST test used by Dr. Baselious was, according to Aladan, not FDA-approved (Def.'s 56.1 Statement ¶ 6 (citing Ex. A at 114:23-25; Ex. C at 10:18-24; Ex. D ¶ 8)), and was processed and analyzed by Dr. Baselious himself rather than by a commercial laboratory (Def.'s 56.1 Statement ¶ 11).

i. FDA Approval

That the RAST test performed by Dr. Baselious was not FDA approved, is not so unambiguous as Aladan's papers suggest. Of the three pieces of evidence cited by Aladan in support of the relevant paragraph of its 56.1 Statement, only one even mentions the FDA. Dr. Steven J. Weiss states in his affidavit that "Dr. Baselious' testimony suggests that his test was not one of the aforementioned, commercially available and FDA approved RAST tests, and I have not seen any evidence that suggests that it was." (Ex. D ¶ 8 (emphasis added.)) Saying that there is evidence that "suggests" the test was not FDA approved is far different from stating conclusively in a 56.1 Statement, as Aladan does, that the test, in fact was not FDA approved. Moreover, Plaintiff's expert, Dr. Epstein, testified that Dr. Baselious' test was commercially available. Regardless, in a

post-Daubert world, whether the RAST test had secured FDA approval goes to weight. See Daubert, 509 U.S. at 588 (rejecting the general acceptance test as "at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony") (internal quotations omitted).

ii. In-House Processing and Analysis

Ms. Adesina does not contest that the test was processed and analyzed by Dr. Baselious in his office and not in a commercial laboratory. Ms. Adesina refers instead to an FDA publication concerning RAST tests, stating that the test is intended for use in laboratories and physicians' offices. (emphasis added.) As with the FDA approval issue, the desirability of in-house versus commercial processing goes to weight, can be explored on cross-examination and, accordingly, does not warrant Daubert exclusion.

c. Fit

Aladan claims that "Dr. Baselious lacked a sufficient factual basis upon which to make his diagnosis." (Def.'s Mem. L. 9.) Defendant emphasizes that the RAST test was administered at the behest of Ms. Adesina's attorneys, and not because Dr. Baselious suspected an allergy. Aladan argues that Ms. Adesina was simply "shopping" for a positive RAST test, and Dr. Baselious obliged. (Def.'s Mem. L. 9.)

Again, these issues go to weight, not admissibility. Daubert and Rule 702 are intended to exclude "junk science." Amorgianos, 303 F.3d at 267. The Court does not find that the RAST test administered by Dr. Baselious, an ear, nose, and throat specialist, is junk science. In addition, the requirement that expert evidence "fit" the facts of the case is really an issue of relevance. Upon any fair reading of Rule 401, the RAST test administered by Dr. Baselious meets the "any tendency" threshold. Aladan's motion to exclude the RAST test and testimony concerning the RAST test is, therefore, denied, as is Aladan's motion for summary judgment asserting Ms. Adesina has no admissible evidence of a latex allergy.

C. Evidence of Type IV Chemical Sensitivity

Ms. Adesina also alleges that she suffers from Type IV contact dermatitis caused by her use of latex gloves (Pl.'s 56.1 Statement ¶ 27.) This condition, though commonly referred to as a Type IV latex allergy, is actually a contact dermatitis caused by exposure to chemicals or antioxidants used in the production of latex gloves and other types of gloves. (Pl.'s 56.1 Statement ¶¶ 27-28.) Type IV contact dermatitis may be diagnosed through a patch test. (Pl.'s 56.1 Statement ¶ 30.) According to Aladan, a patch test is a prerequisite for the diagnosis of Type IV contact dermatitis, and because Ms. Adesina has never undergone a patch test, there is no evidence she suffers from this condition.

(Def.'s 56.1 Statement ¶¶ 31-32.) To support this argument, Aladan cites the Affidavit of Dr. Weiss (Ex. D ¶ 12) and the deposition testimony of Dr. Epstein (Ex. F 321:4-9). Unfortunately for Aladan, neither of the sources cited says that a patch test is a "prerequisite" for diagnosing contact dermatitis and, to the contrary, suggests that a patch test is not essential to the diagnosis.

According to Ms. Adesina, her "opposing papers show that there is ample evidence that [she] was diagnosed properly as having . . . Type IV contact dermatitis." (Pl. Mem. at 4). Frankly, the Court does not see the ample evidence to which Ms. Adesina refers. The evidence cited by Plaintiff in her Memorandum of Law and 56.1 Statement does not directly state that Ms. Adesina suffered from contact dermatitis, but instead usually discusses her symptoms more generally and/or refers just to latex allergy. Nonetheless, as the Court is not an expert on the distinction between latex allergy and contact dermatitis, and because contact dermatitis is often referred to as Type IV latex allergy, the Court will infer in favor of the non-movant, Ms. Adesina, that the evidence cited by Ms. Adesina is in reference to Type IV contact dermatitis. Additionally, the deposition testimony of Dr. Epstein cited by Aladan does explicitly discuss the possibility of Ms. Adesina suffering from Type IV contact dermatitis:

> Q: Other than the fact that she [Ms. Adesina] told you that she suffered a rash on her hands after she used latex gloves, do you have any other basis to conclude that she suffers from the Type IV condition, contact dermatitis?
>
> A: She also had itching with condoms, and that's a local reaction. And in my opinion, it was probably also a Type IV reaction.

(Ex. F 321:17-25.)

Ms. Adesina's claims with regard to Type IV dermatitis may be weak, but whether they pass the preponderance-of-the-evidence test is really a matter for the jury to decide. The motion for summary judgment dismissing Ms. Adesina's Type IV claims is denied.

IV. Motion to Exclude Dr. Epstein's Testimony

Aladan moves to preclude Dr. Ellen Epstein from testifying to the following opinions:

1. Any expert opinion or testimony that the latex gloves manufactured by Defendant[] Aladan Corporation . . . and which are at issue in this case, were defectively designed, manufactured, or labeled;
2. Any expert opinion or testimony that the latex gloves manufactured by Aladan . . . and which are at issue in this case caused any injury to the plaintiff;
3. Any expert opinion or testimony that the plaintiff suffers from a Type I latex allergy;
4. Any expert opinion or testimony that is based in whole or in part on the purported positive 'RAST' test, or any references thereto;
5. Any expert opinion or testimony that the plaintiff suffers from a Type IV chemical hypersensitivity; and
6. Any expert opinion or testimony that any

> purported Type IV chemical hypersensitivity was caused by the plaintiff's use of the latex gloves manufactured by Aladan . . . that are at issue in this case.

(Def.'s Mem. L. 1-2.)

Dr. Epstein's competence and qualifications as a reliable allergist are not under attack. Instead, Aladan challenges Dr. Epstein's ability to give opinions 1, 2, and 6, listed above, on the ground that such opinions are out of Dr. Epstein's area of expertise. "By her own admission, Dr. Epstein is not an expert in the design, manufacture or labeling of latex gloves." (Def.'s Mem. L. 2.) Because Daubert requires an expert to be qualified in the field about which he or she will testify, the Court concludes that Dr. Epstein cannot testify as to opinion 1 listed above. Dr. Epstein can testify, however, as to opinions 2 and 6, to the extent such testimony stems from her expertise as an allergist and does not require her to become an armchair expert on the design, manufacturing, or labeling of latex gloves.

Aladan challenges Dr. Epstein's ability to testify on opinions 3, 4, and 5, on the same bases Aladan challenged the admissibility of the RAST test and Ms. Adesina's ability to produce admissible evidence of Type I latex allergy and Type IV chemical hypersensitivity in Motion IV. Defendant's papers merely rehash issues from the previous motion and offer no challenges specific to Dr. Epstein or that suggest Dr. Epstein, as an allergist, is not qualified to testify on these issues.

Therefore, Dr. Epstein is permitted to testify as to opinions 3, 4, and 5, and opinions 2 and 6, as limited above.

V. Motion for Summary Judgment or Partial Summary Judgment on Whether There Is Evidence of Product Defect

Aladan moves for summary judgment on the basis that Ms. Adesina has not designated an expert to present evidence of defects and has not presented admissible evidence of defects in Aladan's latex gloves. Each of plaintiff's four causes of action is premised on an allegation that the latex gloves were defective or not of merchantable quality. Aladan contends that Plaintiff's Rule 26 disclosure does not disclose any expert with specific knowledge or expertise regarding Aladan's design, manufacturing, or labeling. Additionally, no reports were produced that provide information about Defendant's specific design and manufacturing process. (Def's Mem. L. 2-3.)

The Court, relying on its previous overview of the summary judgment standard, sets forth the defective product and merchantability standards below.

A. Defective Product Standards

For claims of strict products liability, negligence, or breach of an implied warranty, "the plaintiff must prove that the product was defective as a result of either a manufacturing flaw, improper design, or a failure to provide adequate warnings

regarding use of the product." Langer v. Well Done, Ltd., No. 05 Civ. 7491, 2006 WL 462125, at *2 (N.Y. Sup. Ct. Jan. 31, 2006); accord Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 252 (E.D.N.Y. 1999).

1. Mistake in Manufacturing

To utilize this theory, a plaintiff must show that the product unit was defective because of "some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction." Carpara v. Chrysler Corp., 52 N.Y.2d 114, 129 (N.Y. 1981).

2. Improper Design

To prevail on a theory of improper design, a plaintiff must present evidence that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." Colon ex rel. Molina v. BIC USA, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001).

3. Failure to Warn

To prove that a product was defective due to a failure to warn, a claimant must show "(1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm." Id. at 84.

B. Breach of Express Warranty Standard

Whereas each of the three theories described above relates to a product defect,

> Liability for breach of express warranty does not depend so much on the existence of a product "defect" as it does on the existence of a misrepresentation. For this reason, plaintiff in an express warranty case does not have to prove a "defect" so much as he has to prove that the product did not perform in accord with a promise voluntarily made by the defendant.

1 Michael Weinberger, New York Products Liability § 15.2 (2d ed. 1982).

C. Analysis

1. Defective Product Theories

Aladan argues that because Plaintiff has not disclosed a human factors or manufacturing expert, Ms. Adesina cannot show that (1) there was a defect; (2) the gloves were unsafe; (3) the gloves were not fit or merchantable; or (4) there was a warning defect. Ms. Adesina argues that she has disclosed expert witnesses qualified to testify on these issues.

a. Dr. Epstein's Testimony

Plaintiff claims that Dr. Epstein, an allergist, will testify as to whether the latex gloves were defectively designed, manufactured, or labeled. As the Court already held in the Daubert challenge in Motion IV, such testimony is too far afield from Dr. Epstein's area of expertise to be reliable, and is not permitted.

b. Judge Ludwig's MDL Ruling

Plaintiff also argues that Aladan ignores Judge Ludwig's ruling in the MDL case from which this case was remanded. Judge Ludwig issued a ruling that Charles Kyper's generic expert testimony concerning FDA regulatory and compliance issues is admissible. In re Latex Gloves Products Liability Litigation, No. 1148, 2002 WL 992037 (E.D. Pa. May 10, 2002). Judge Ludwig's ruling permits Mr. Kyper's testimony

> that latex glove manufacturers and distributors were subject to statutory and regulatory obligations to inform healthcare workers of the risks of glove use, including the giving of timely warnings of the dangers of Type I hypersensitivity reactions; that their claims as to hypoallergenicity were misleading; and that they had a duty to report incidents to the FDA showing the potential for serious injury or death arising from glove use.

Id. Mr. Kyper also sought to testify that FDA employees who advised manufacturers not to place warning labels on their NRL glove products violated the federal Government Service Code of Ethics. As to this opinion, Judge Ludwig ruled that, unless properly predicated under Rule 703, this hearsay testimony would be excluded as incompetent. Id.

Because of Judge Ludwig's ruling, Plaintiff asserts that she has, at least, some evidence to support her product defect claims. Aladan replies that, regardless of Judge Ludwig's ruling, Ms. Adesina's product defect claims must fail as a matter of law because no MDL experts have testified about Aladan's

specific manufacturing processes. Because the product defect standard based on a failure to warn theory set forth above does not require defendant-specific information for Ms. Adesina to prevail, Aladan's last point is yet another piece of evidence for the jury to weigh. The Court denies summary judgment dismissing Ms. Adesina's product defect claims.

2. Breach of Express Warranty Theory

Though Aladan discusses this standard in its motion, it offers no substantive argument to support its motion for summary judgment on this ground. As a result, Aladan has not met its burden as the summary judgment movant, and summary judgment dismissing Ms. Adesina's breach of express warranty claim is denied. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

VI. Motion to Exclude Testimony of Charles Kyper

Aladan moves pursuant to Daubert to exclude the testimony of Charles Kyper, the founder of a medical device regulatory consulting firm. Mr. Kyper worked at the FDA for twenty-eight years, most recently as Associate Director for Regulatory Affairs in the Division of Small Manufacturers Assistance and as Assistant Director for Compliance in the Office of Device Evaluation. (Ex. B at D.)

Mr. Kyper will testify that (1) NRL glove

manufacturers/distributors had statutory or regulatory obligations to warn of the risk of NRL allergic reactions; (2) manufacturers who made claims relating to "hypoallergenic" on NRL glove labels misled users; and (3) FDA employees who advised manufacturers not to place warning labels on their NRL glove products violated the federal Government Service Code of Ethics.

Aladan argues Mr. Kyper's testimony should be excluded under Daubert. First, Aladan argues Mr. Kyper is not qualified because he lacks personal knowledge and expertise, is not an immunologist, allergist or ethicist, and was not involved with NRL gloves while at the FDA. Second, Aladan claims Mr. Kyper's opinions are unreliable because he never analyzed Defendant's product labels, medical literature, product complaints, or key FDA regulations. Third, Aladan asserts Mr. Kyper's opinion that glove manufacturers violated federal statutes and regulations is a conclusion of law that does not assist the factfinder. Finally, Aladan argues that Mr. Kyper's ethics opinions must be excluded as irrelevant.

Plaintiff responds citing Judge Ludwig's denial of a Daubert motion to exclude Mr. Kyper's testimony with regard to opinions 1 and 2, listed above. Plaintiff argues that Judge Ludwig's ruling is binding on the current proceedings. Defendant responds that Judge Ludwig's ruling was "generic and not case specific," as stated in footnote 1 to that opinion.

According to the Manual for Complex Litigation, "[a]lthough the transferor court has the power to vacate or modify rulings made by the transferee judge, subject to comity and 'law of the case' considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings." Manual for Complex Litigation § 20.133 (4th ed. 2004). Moreover, "[i]f transferor judges were permitted to upset rulings of transferee judges, the result would be an undermining of the purpose and usefulness of transfer under Section 1407 . . . ." Stanley Weigel, The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts, 78 F.R.D. 575, 577 (1978). This Court finds no reason to deviate from Judge Ludwig's Daubert findings regarding Mr. Kyper's testimony.

As the Court stated previously in this decision, the purpose of Daubert is to exclude junk science. From Mr. Kyper's curriculum vitae and expert report (Ex. B at C), he appears qualified to testify on opinions 1 and 2 listed above, as Judge Ludwig ruled. Mr. Kyper's testimony on opinion 3, is prohibited, unless Ms. Adesina satisfies Judge Ludwig's invitation to properly predicate, under Rule 703.

Conclusion

For the foregoing reasons, Aladan's summary judgment motions are denied, Aladan's motion to exclude the testimony of

Dr. Epstein is denied in part and granted in part, and Aladan's motion to exclude the testimony of Mr. Kyper is granted in part and denied in part. The parties are directed to appear before the Court for a scheduling conference on July 27 at 9:30 AM.

SO ORDERED.

Dated: New York, New York
July 7 , 2006

JOHN F. KEENAN
United States District Judge